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EXAMINER	
DUFFY, PATRICIA ANN	
ART UNIT	**PAPER NUMBER**
1645	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/077,137	JEFFREY ET AL.	
	Examiner	Art Unit	
	Patricia A. Duffy	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 December 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,7-11,15 and 19-31* is/are pending in the application.

4a) Of the above claim(s) *1,4,7-11 and 15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1, 4, 7-11, 15, 19-31* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 February 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2x02; 1x04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The amendment and response filed 12-17-04 have been entered into the record. Claims 1, 4, 7-11, 15, 19-31 are pending. Claims 19-21 are under examination.

It is noted that Applicants recent communications reference the incorrect serial number (10/077,173) in the upper right hand header of the documents. Applicants should ensure that the submitted documents recite the correct serial number, 10/077,137, so that the response does not get inadvertently matched with the incorrect application.

Priority

Applicant's claim for domestic priority for 60/149,378 under 35 U.S.C. 119(e) is acknowledged. However, the provisional application upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for claims 19-31 of this application. This provisional document does not have written description for the reasons set forth below and further does not enable pharmaceutical use of any BAFF-R polypeptide or fragment thereof. Applicant's claim for domestic priority for 60/181,684 under 35 U.S.C. 119(e) is acknowledged. However, the provisional application upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for claims 19-31 of this application. This provisional document does not have written description for the reasons set forth below and further does not enable pharmaceutical use of any BAFF-R polypeptide or fragment thereof for any of the diseases or disorders contemplated in the specification as filed. Applicant's claim for domestic priority for 60/183,536 under 35 U.S.C. 119(e) is acknowledged. However, the provisional application upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for claims 19-31 of this application. This provisional document does not have written description for the reasons set forth below and further does not enable pharmaceutical use of any BAFF-R polypeptide or fragment thereof for any of the diseases or disorders as contemplated in the specification. As to

the claim for priority under 35 U.S.C. 120, this prior application lacks written description for reasons set forth supra and is not enabled for the scope as set forth herein.

As such, claims 19, 20, 21, 23, 24, 26, 27-31 are accorded the instant filing date for prior art purposes. Claims 22, and 25 are accorded the filing date of PCT/US00/22507 of 8/16/00 for prior art purposes.

Drawings

The drawings in this application have been approved by the Draftsperson. No further action is required by Applicants.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application, by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because: it has not been signed by inventor Fabienne MacKay. Correction of this defect is required.

Information Disclosure Statement

The two information disclosure statements filed November 18, 2002, have been considered with the exception of reference BA, a copy of which has not been provided. It is noted that the copy indicates as reference BA is in fact a duplicate copy of reference BB. The information disclosure statement filed July 13, 2004 has been considered. Initialed copies are enclosed.

Election/Restrictions

Applicant's election with traverse of Groups V, claims 19-21 in the response filed 12-17-04 is acknowledged. The traversal is on the ground(s) that Groups I and II are not

separate because BAFF-R is in fact BCMA. This is found persuasive and the requirement between Groups I and II is withdrawn. With respect to the election of Group IV, claims 19-21, Applicants request that should the claims of Groups IV be found allowable, they request rejoinder and request that the Examiner telephone prior to rejoinder so that appropriate amendments to the rejoined claims can be made. The request for rejoinder is noted, however none of the claims are in condition for allowance at this time. Further, as set forth in the restriction requirement it is Applicants responsibility to maintain dependency on the product claims or to otherwise include the limitations of the product claims during prosecution and failure to do so may result in the loss of the right to rejoinder.

The requirement for restriction between the product and process claims is still deemed proper and is therefore made FINAL.

Claims 1, 4, 7-11, and 15 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the response filed 12-17-04.

Claim Objections

Claims 19-31 are objected to because of the following informalities: the claims use the acronyms "BAFF-R" and "BAFF" without first defining what it represents in independent claim 19. While the claims can reference acronyms, the material represented by the acronym must be clearly set forth at the first use of the acronym. Amendment of claim 19 to recite B cell activating factor receptor (BAFF-R) or other defining terminology that has particular written description support in the specification as filed would overcome the objection. Appropriate correction is required.

Double Patenting

Claims 19-31 of this application conflict with claims 12 of Patent Application Publication 2004/0072188 and claims 106, 107 and 151 of Application No. 10/380,703. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 19-31 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 106, 107, and 151 of

copending Application No. 10/380,703. Although the conflicting claims are not identical, they are not patentably distinct from each other because the genus contemplated by the '703 application anticipates the instantly claimed genus because the BAFF-R sequence of SEQ ID NO:10 of the '703 application is 100% identical as compared with SEQ ID NO:1 recited in the instant claims. SEQ ID NO:11 of the '703 application encodes a BAFF-R (SEQ ID NO:11 extracellular domain) fused to the Fc region of an immunoglobulin.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 19, 20, 21, 23, 24, 26, 27-31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the

application was filed, had possession of the claimed invention. This is a written description rejection.

The claims are drawn to pharmaceutical compositions comprising BAFF-R polypeptides, fragments thereof and or sequences that have a recited percent identity as compared with SEQ ID NO:1 or particular fragments thereof and immunoglobulin fusion proteins. The specification teaches a single nucleic acid (SEQ ID NO:2) encoding a "BAFF-R" polypeptide of SEQ ID NO:1 from humans that was demonstrated to bind BAFF (also known as Tall-1, BlyS, zTNF4, neutrokine alpha). The specification does not place any structure, chemical or functional limitations on the variants of BAFF-R. (see page 7 of specification). The recitation of "BAFF-R" does not convey a common structure or function. The mammalian genus of BAFF-R polypeptides is not described in the specification as filed. The scope of the claims includes numerous structural variants and naturally occurring mammalian homologues, and the genus is highly variant because a significant number of structural differences between genus members is permitted. Although the specification teaches that variants can be readily screened, the specification and the claim do not provide any guidance on the structure of the polypeptide and what changes can or can not be made. Structural features that could distinguish compounds in the genus from others in the protein class are missing from the disclosure and the claims. No common structural attributes identify the members of the genus. The general knowledge and level of skill in the art do not supplement the omitted description, because specific, not general guidance is needed. Since the disclosure fails to describe the common attributes or structural characteristics that identify members of the genus, and because the genus is highly variant, the function of the binding of antibody alone is insufficient to describe the genus of BAFF-R polypeptides of that function equivalently. One of skill in the art would reasonable conclude that the disclosure of a single SEQ ID NO:1, fails to provide a representative number of species of BAFF-R to describe the claimed genus of variants. Applicants were not in possession of the claimed genus because

the specification does not convey to one of skill in the art a representative number of variants in structure and function of any such polypeptide that has the claimed/structure and function. The genus of polypeptides with the claimed function is substantial and highly variant because the polypeptides do not have a common structure and function. The recitation of "BAFF-R" does not convey a common structure nor a common function. Claims 20, 21, 23-31 are directed to encompass corresponding sequences from other species, mutated sequences, allelic variants, splice variants, sequences that have a recited degree of identity (similarity, homology), and fragments of amino acid residues 8-41 of SEQ ID NO:1 that bind BAFF and so forth. None of these sequences meet the written description provision of 35 USC 112, first paragraph. The specification provides insufficient written description to support the genus encompassed by the claims. Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.). With the exception of SEQ ID NO:1 and particularly disclosed B cell activating factor binding fragments thereof and IgFc fusions thereof, the skilled artisan cannot envision the detailed chemical structure of the encompassed polypeptides, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmacentical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence. As such the specification lacks written description for genus of BAFF-R polypeptides or claimed

variants and fragments, one skilled in the art would not recognize that applicants had possession of the genus of claimed polypeptides for therapeutic use as instantly claimed. The specie and particularly disclosed fragments thereof specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

Claims 19-31 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a pharmaceutical composition comprising an isolated B cell activating factor receptor (BAFF-R) of SEQ ID NO:1 or a fragment comprising residues 1-51 of SEQ ID NO:1 that binds B cell activating factor (BAFF), wherein the BAFF-R is optionally fused to the Fc region an immunoglobulin it does not reasonably provide enablement for sequence variants, naturally occurring variants, allelic variants, mammalian homologues or percent variants thereof and fusions to an immunoglobulin per se. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The written description of a BAFF-R is limited to the protein sequence (SEQ ID NO:1 which functions to bind the ligand BAFF. The specification teaches that a BAFF residues 1-51 when fused to an Fc region of an immunoglobulin is effective to inhibit the binding of BAFF to its cognate receptor on the surface of cells and reduces progression to severe nephritis in an autoimmune murine model of lupus. The specification fails to provide an enabling written description of any other polypeptides or fragments of 1-51 of SEQ ID NO:1 within the plethora of encompassed variants, which function equivalently to the disclosed SEQ ID NO:1 and the 1-51 residue fragment thereof, in any of the in vivo or in vitro activity assays. The specification fails to provide an enabling written description of any variant, derivative or homolog of BAFF-R as represented by SEQ ID NO:1, or provide

any chemical description of any other functional equivalent of the protein set forth in SEQ ID NO:1. The specification fails to provide a written description of any other mammalian homologs or provide reason to believe that more likely than not functional equivalents are present in other mammals which would have the identical functional properties as the human BAFF-R (SEQ ID NO:1). The specification fails to teach the critical protein residues involved in the function of the protein SEQ ID NO:1, such that the skilled artisan could even begin to test or screen for sequence homologs, variants or derivatives which would be functional equivalents of SEQ ID NO:1 using conventional technology. Thus, one of skill in the art would be reduced to merely randomly altering amino acid(s) which would lead to unpredictable results regarding the functional activity of the protein. Protein chemistry is probably one of the most unpredictable areas of biotechnology and the art teaches that the significance of any particular amino acid and sequences for different aspects of biological activity can not be predicted *a priori* and must be determined empirically on a case by case basis (Rudinger et al, in "PEPTIDE HORMONES", edited by Parsons, J.A., University Park Press, June 1976, page 6). The art specifically teaches that even a single amino acid change in a protein leads to unpredictable changes in the biological activity of the protein. For example, replacement of a single lysine residue at position 118 of the acidic fibroblast growth factor by glutamic acid led to a substantial loss of heparin binding, receptor binding, and biological activity of the protein (Burgess et al., The Journal of Cell Biology, 111:2129-2138, 1990). In transforming growth factor alpha, replacement of aspartic acid at position 47 with alanine, or asparagine did not affect biological activity while replacement with serine or glutamic acid sharply reduced the biologic activity of the mitogen (Lazar et al., Molecular and Cellular Biology, 8(3):1247-1252, 1988). These references demonstrate that even a single amino acid substitution or what appears to be an inconsequential chemical modification, will often dramatically affect the biological activity of a protein. The specification has not conceived any other functionally equivalent protein sequences. The art does not teach any

appropriate variants within the claimed scope of invention. Conception is a question of law and like conception of any chemical substance, the conception of a protein requires definition of the substance other than by its functional utility. Since, the specification lacks a clear written description of a chemical structure of functional allelic variants or other proteins or polynucleotides having at least 80%, 90% or 95% homology, it is not enabled for this language because it fails to enable the skilled artisan to envision the detailed chemical structure of the claimed protein or DNA sequences coding for these proteins, as well as the method of obtaining it, and therefore conception is not achieved until reduction to practice has occurred (*Fiers v Revel*, 25 USPQ2d 1601 (CAFC 1993)). In view of the lack of enabling written description of how to obtain, make and use the protein homologs or DNA encoding the homologs, allelic variants or polynucleotides comprising a polynucleotide having claimed percent homology one of skill in the art would be unable to produce either the proteins encompassed by the percent homology or immunoglobulin chimeric proteins comprising these sequence homologs, since the production of chimeric proteins requires the specific DNA sequence encoding the particular protein homolog(s).

In view of the lack of specific written description of conception of protein or DNA homologs, the lack of an enabling written description of how to obtain, make and use the protein homologs or the DNA encoding the protein homologs in order to obtain chimeric homologous proteins having at least 80% or 90% sequence identity SEQ ID NO:1 or fragments thereof, the unpredictability associated with producing and using the myriad of homologs encompassed in the scope of the claims, the lack of to teach even a beginning point for variation of the protein sequence for routine experimentation, lack of working examples commensurate in scope with the instant claims, the skilled artisan would be forced into undue experimentation to practice (i.e. make and use) the invention as is broadly claimed.

Claims 19-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to claim 19-31, the claims recite the term 'therapeutically effective amount" but it is unclear what therapeutic effect is achieved. As such, the skilled artisan would not be readily apprised of the metes and bounds of this amount and would not know if they were infringing the invention.

As to dependent claims 20, 22, 23-26 and 31 are confusing because they use "fragment language" that does not have clear and unambiguous basis in claim 19. Does Applicant intend to properly limit the fragment of claim 19 ?. Claim 20 indicated that the isolated BAFF-R polypeptide is selected from a) - e). What is missing from the preamble is reference to the "fragment" as recited in the independent claim. As such, the "fragment" language of the dependent claim apparently lacks clear antecedent basis.

It is noted that the phrase "capable of binding to BAFF" has been interpreted based on the common dictionary definition of "having the ability" and is therefore viewed a positive recitation of specific function in the claims. If Applicants wish to dispute this interpretation, they should provide an alternative interpretation and argue such for the record.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 19-21 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Bram et al (US Patent No 5,969,102, issued October 19, 1999).

The claims are drawn to pharmaceutical compositions comprising BAFF-R or binding fragments thereof optionally fused to an immunoglobulin constant region, and wherein BAFF-R is a particular fragment or at least 80% or 90% identical with the SEQ ID NO:1 or fragment thereof. It is noted that these claims have been assigned the instant filing date for prior art purposes (see "Priority" section above).

Bram et al teach chimeric TACI proteins that are joined to the Fc domain of an immunoglobulin (column 17, lines 10-20). Bram et al teach therapeutic methods and compositions comprising dominant negative forms of TACI to treat cancer, autoimmune diseases, and inflammation by using the free extracellular domain. Bram et al contemplate pharmaceutical compositions comprising these (columns 41-42) with a variety of pharmaceutically acceptable carriers. TACI inherently binds BAFF and is therefore a BAFF - receptor and is documented as such by multiple publications already of record. Since the claims do not require specific sequence nor specifically defined binding fragments, the compositions contemplated by Bram et al anticipated the instantly claimed invention and TACI-Fc comprises a fragment of SEQ ID NO:1 or variant thereof (i.e. as it relates to claim 20.

Claims 18-21, 23, 24, 26-31 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Gross et al (WO/00/40716, published 13 July 2000).

The claims are drawn to pharmaceutical compositions comprising BAFF-R or binding fragments thereof optionally fused to an immunoglobulin constant region, and wherein BAFF-R is a particular fragment or at least 80% or 90% identical with the SEQ ID NO:1 or fragment thereof. It is noted that these claims have been assigned the instant filing date for prior art purposes (see "Priority" section above).

Gross et al teach pharmaceutical compositions comprising SEQ ID NO:8 or fragments thereof fused to a constant region of an immunoglobulin and a pharmaceutically acceptable carrier (page 2, line 15-page 3, line 29; paragraph bridging pages 83-84 and Example 6, beginning on page 94). SEQ ID NO:8 of Gross et al is 100% identical as compared to SEQ ID NO:1 of the instantly claimed invention and as such the pharmaceutical composition comprising BMCA-Fc fusion protein of Gross et al anticipates the instantly claimed invention. Given the open language of the "fragments", it is noted that aside from SEQ ID NO:8 of the prior art, the other contemplated pharmaceutical compositions comprising extracellular domains of other BAFF/zTNF4/Blys/Tall-1 - binding polypeptides comprise "a fragment" of SEQ ID NO:1 and therefore, these other fusions read on the claims as they relate to the fragment embodiment of the claims. It is noted that pharmaceutical compositions comprising these fusions have written description in the priority document 09/226,533 filed 07 January 1999.

Claims 22 and 25 are rejected under 35 U.S.C. 102(a) as anticipated by Gross et al (WO/00/40716, published 13 July 2000). It is noted that these claims have been assigned the filing date of PCT/US00/22507 of 8/16/00 for prior art purposes (see "Priority" section above). The claims are drawn to SEQ ID NO:1, residues 1-184 or fragments thereof capable of binding to BAFF or SEQ ID NO:1, residues 1-51. It is noted that the composition comprising BCMA-Fc fusions with a pharmaceutically acceptable carrier as disclosed in the Gross et al publication as set forth directly above anticipate the instantly claimed invention.

Claims 19-31 are rejected under 35 U.S.C. 102(e) as anticipated by Shu et al (U.S. Patent No. 6,475,987, issued November 5, 2000, filed May 5, 2000 with benefit of priority to May 1, 2000, provisional application 60/201,012).

The claims are drawn to pharmaceutical compositions comprising BAFF-R or binding fragments thereof optionally fused to an immunoglobulin constant region, and wherein BAFF-R is a particular fragment or at least 80% or 90% identical with the SEQ ID NO:1 or fragment thereof. The claims are also drawn to SEQ ID NO:1 and particular fragments thereof.

Shu et al teach pharmaceutical compositions comprising a pharmaceutically acceptable carrier and variants of at least about 60% identical to SEQ ID NO:11 that are less than 100% identical to an amino acid sequence selected from the group consisting of SEQ ID NO:11 and 17. Therefore, this language anticipates the instantly claimed invention because it reads of fragments of SEQ ID NO:11 and variants thereof (see in particular claim 10). SEQ ID NO:11 is identical as compared to the instant SEQ ID NO:1. Shu et al define Tall-1 receptor to include any full length TALL-1 receptor protein, fusion proteins or any homologue of such a protein (column 22, lines 42-67; column 24, lines 8-44) or fragments thereof fused to a constant region of an immunoglobulin and a pharmaceutically acceptable carrier (column 26, line 39-column 30, line 8 and Example 4, column 46-47). The fragment of SEQ ID NO:11 of Shu et al is 100% identical as compared to SEQ ID NO:1 fragment of the instantly claimed invention and as such the pharmaceutical composition comprising BMCA-Fc fusion protein of Example 4 anticipates the instantly claimed invention.

Please note: when the claims of the reference U.S. patent or U.S. patent application publication and the application are directed to the same invention or are obvious variants, an affidavit or declaration under 37 CFR 1.131 is not an acceptable method of overcoming the rejection.

Claims 19-31 are rejected under 35 U.S.C. 102(e) as anticipated by Shu et al (U.S. Patent Application Publication 2003/0148445 A1, published August 7, 2003, with benefit of priority to May 1, 2000, provisional application 60/201,012).

The claims are drawn to pharmaceutical compositions comprising BAFF-R or binding fragments thereof optionally fused to an immunoglobulin constant region, and wherein BAFF-R is a particular fragment or at least 80% or 90% identical with the SEQ ID NO:1 or fragment thereof. The claims are also drawn to SEQ ID NO:1 and particular fragments thereof.

The teachings of Shu et al are identical to that of the Shu et al patent as set forth above. Shu et al teach pharmaceutical compositions comprising a pharmaceutically acceptable carrier and variants of at least about 40% identical to SEQ ID NO:11 that are less than 100% identical to an amino acid sequence selected from the group consisting of SEQ ID NO:11 and 17 or a TALL-1 receptor. Therefore, this language anticipates the instantly claimed invention because it reads of fragments of SEQ ID NO:11 and variants thereof (see in particular claims 50-58). SEQ ID NO:11 is identical as compared to the instant SEQ ID NO:1. Shu et al define Tall-1 receptor to include any full length TALL-1 receptor protein, fusion proteins or any homologue of such a protein ([0098]) or fragments thereof fused to a constant region of an immunoglobulin and a pharmaceutically acceptable carrier ([0105] and Example 4, [0179-0182]). The fragment of SEQ ID NO:11 of Shu et al is 100% identical as compared to SEQ ID NO:1 fragment of the instantly claimed invention and as such the pharmaceutical composition comprising BMCA-Fc fusion protein of Example 4 anticipates the instantly claimed invention.

Please note: when the claims of the reference U.S. patent or U.S. patent application publication and the application are directed to the same invention or are obvious variants, an affidavit or declaration under 37 CFR 1.131 is not an acceptable method of overcoming the rejection.

Status of the Claims

Claims 1, 4, 7-11 and 15 are withdrawn from consideration. Claims 19-31 stand rejected.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy whose telephone number is 571-272-0855. The examiner can normally be reached on M-Th 6:30 am - 6:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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